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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/771,382

01/25/2001

Ian Richard Anselm Peak

8795-24 U1

6450

570

7590

11/26/2008

PANITCH SCHWARZE BELISARIO & NADEL LLP  
ONE COMMERCE SQUARE  
2005 MARKET STREET, SUITE 2200  
PHILADELPHIA, PA 19103

EXAMINER

FORD, VANESSA L

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

11/26/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/771,382	<b>Applicant(s)</b> PEAK ET AL.	
	<b>Examiner</b> VANESSA L. FORD	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 33,34,49-52,54,55 and 57-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 33,34,49-52,54,55 and 57-60 is/are allowed.
- 6) ☒ Claim(s) 61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **FINAL ACTION**

1. This action is responsive to Applicant's amendment and response filed August 8, 2008. Claims 54, 57, 59 and 60 have been amended. Claims 1-32, 35-48, 53 and 56 have been canceled. Claim 61 has been added.

Claims under examination are 33-34, 49-52, 54-55 and 57-61 are under examination.

### ***Rejections Withdrawn***

2. In view of Applicant's amendment and response the following rejections:

a) rejection of claims 54-55 and 57-60 under 35 U.S.C. 112, first paragraph (scope of enablement), pages 3-10, paragraph 3 of the previous Office action.

b) rejection of claims 54-55 and 57-60 under 35 U.S.C. 112, first paragraph (written description) pages 10-17 paragraph 4 of the previous Office action.

### ***New Grounds of Rejection Necessitated by Applicant's Amendment***

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Art Unit: 1645

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claim 61 is rejected under 35 U.S.C. 102(a) as anticipated by Masignani et al (*WO 99/36544 published July 22, 1999*).

Claim 61 is directed to an isolated protein having at least 90% sequence identity to SEQ ID NO:23 or SEQ ID No.35, wherein the isolated protein is immunogenic.

Masignani et al teach proteins from *Neisseria meningitidis* and immunogenic compositions as well as pharmaceutical compositions containing the polypeptide (see the Abstract and pages 29-30). Masignani et al teach that fusion protein that can provide an alternative to direct protein expression (page 20). Masignani et al teach a *N. meningitidis* protein ORF40-1 protein (SEQ ID NO:4) that has the amino acid sequence that is 98.1% identity to SEQ ID NO:23. See the sequence alignment below:

```

Query Match          98.1%;  Score 2550.5;  DB 2;  Length 591;
Best Local Similarity 86.6%;  Pred. No. 4.1e-150;
Matches 512;  Conservative 0;  Mismatches 0;  Indels 79;  Gaps
1;

Qy          1 MNKIYRIIWNNSALNAWVVVSELTRNHTKRASATVKTAVLATLLFATVQASANNE----- 54
              ||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MNKIYRIIWNNSALNAWVVVSELTRNHTKRASATVKTAVLATLLFATVQASANNEEQEEDL 60

Qy          55 ----- 54

Db          61 YLDPVQRTVAVLIVNSDKEGTGEKEKVEENS DWAVYFNEKGVLTAREITLKAGDNLKIKQ
120

Qy          55 -----TDLTSVGTEKLSFSANGNKVNITS DTKGLNFAKETAGTNGDTTVHLN
101
              ||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          121 NGTNFTYSLKKDLTDLTSVGTEKLSFSANGNKVNITS DTKGLNFAKETAGTNGDTTVHLN
180

Qy          102 GIGSTLTDTLNLTGATTNVTNDNVTDDDEKKRAASVKDVLNAGWNIKGVPKGT TASDNVDF
161
              ||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          181 GIGSTLTDTLNLTGATTNVTNDNVTDDDEKKRAASVKDVLNAGWNIKGVPKGT TASDNVDF
240

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Art Unit: 1645

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Qy      162 VRTYDTVEFLSADTKTTTVNVESKDNKGKTEVKIGAKTSVIKEKDGKLVTKDKGENGSS
221
      |||
Db      241 VRTYDTVEFLSADTKTTTVNVESKDNKGKTEVKIGAKTSVIKEKDGKLVTKDKGENGSS
300

Qy      222 TDEGEGLVTAKEVIDAVNKAGWRMKTTTANGQTGQADKFETVTSGTNVTFASGKGTTATV
281
      |||
Db      301 TDEGEGLVTAKEVIDAVNKAGWRMKTTTANGQTGQADKFETVTSGTNVTFASGKGTTATV
360

Qy      282 SKDDQGNITVMYDVNVGDALNVNQLQNSGWNLDSKAVAGSSGKVISGNVSPSKGKMDETV
341
      |||
Db      361 SKDDQGNITVMYDVNVGDALNVNQLQNSGWNLDSKAVAGSSGKVISGNVSPSKGKMDETV
420

Qy      342 NINAGNNIEITRNGKNIDIATSMTPQFSSVSLGAGADAPTLSVDGDALNVGSKKDNKPVR
401
      |||
Db      421 NINAGNNIEITRNGKNIDIATSMTPQFSSVSLGAGADAPTLSVDGDALNVGSKKDNKPVR
480

Qy      402 ITNVAPGVKEGDVTNVAQLKGVAQNLNNRIDNVDGNARAGIAQAIATAGLVQAYLPGKSM
461
      |||
Db      481 ITNVAPGVKEGDVTNVAQLKGVAQNLNNRIDNVDGNARAGIAQAIATAGLVQAYLPGKSM
540

Qy      462 MAIGGGTYRGEAGYAIGYSSISDGGNWI IKGTASGNSRGHFGASASVGYQW 512
      |||
Db      541 MAIGGGTYRGEAGYAIGYSSISDGGNWI IKGTASGNSRGHFGASASVGYQW 591

```

Masignani et al teach a *N. meningitidis* protein ORF40-1 protein (SEQ ID NO:4)

that has the amino acid sequence that is 99.3% identity to SEQ ID NO:35. See the sequence alignment below:

```

Query Match          99.3%;  Score 2333;  DB 2;  Length 591;
Best Local Similarity 100.0%;  Pred. No. 5.5e-140;
Matches 458;  Conservative 0;  Mismatches 0;  Indels 0;  Gaps
0;

Qy      4  TDLTsvgTEKLSFSANGKNVNITSdTKGLNFAKETAGTNGDttVHLNGIGSTLTdtLLNT 63
      |||
Db      134 TDLTsvgTEKLSFSANGKNVNITSdTKGLNFAKETAGTNGDttVHLNGIGSTLTdtLLNT
193

```

Art Unit: 1645

Qy 64 GATTNVTNDNVTDDDEKKRAASVKDVLNAGWNIKGVPKPGTTASDNVDFVRTYDTVEFLSAD  
123  
|  
Db 194 GATTNVTNDNVTDDDEKKRAASVKDVLNAGWNIKGVPKPGTTASDNVDFVRTYDTVEFLSAD  
253

Qy 124 TKTTTVNVESKDNGKKTEVKIGAKTSVIKEKDGLVTGKDKGENGSSTDEGEGLVTAKEV  
183  
|  
Db 254 TKTTTVNVESKDNGKKTEVKIGAKTSVIKEKDGLVTGKDKGENGSSTDEGEGLVTAKEV  
313

Qy 184 IDAVNKAGWRMKT TTTANGQTGQADKFETVTS GTNVT FASGK GTTATVSKDDQGNITVMYD  
243  
|  
Db 314 IDAVNKAGWRMKT TTTANGQTGQADKFETVTS GTNVT FASGK GTTATVSKDDQGNITVMYD  
373

Qy 244 VNVGDALNVNQLQNSGWNLD SKAVAGSSGKVISGNVSPSKGKMDETVNINAGNNIEITRN  
303  
|  
Db 374 VNVGDALNVNQLQNSGWNLD SKAVAGSSGKVISGNVSPSKGKMDETVNINAGNNIEITRN  
433

Qy 304 GKNIDIATSMTPQFSSVSLGAGADAP T LSV DGDALNVGSKKDNKPVRITNVAPGVKEGDV  
363  
|  
Db 434 GKNIDIATSMTPQFSSVSLGAGADAP T LSV DGDALNVGSKKDNKPVRITNVAPGVKEGDV  
493

Qy 364 TNVAQLKGVAQN LNNRIDNVDGNARAGIAQAIATAGLVQAYLP GKSMMAIGGGTYRGEAG  
423  
|  
Db 494 TNVAQLKGVAQN LNNRIDNVDGNARAGIAQAIATAGLVQAYLP GKSMMAIGGGTYRGEAG  
553

Qy 424 YAIGYSSISDGGNWIIKGTASGNSRGHFGASASVGYQW 461  
|  
Db 554 YAIGYSSISDGGNWIIKGTASGNSRGHFGASASVGYQW 591

The protein and pharmaceutical compositions of Massignani et al appear to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's protein and pharmaceutical compositions with the protein and

Art Unit: 1645

pharmaceutical compositions of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein and pharmaceutical compositions of the prior art does not possess the same material structural and functional characteristics of the claimed protein and pharmaceutical compositions). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

4. Claim 61 is rejected under 35 U.S.C. 102(a) as anticipated by Peak et al (*WO 99/31132 published June 24, 1999*).

Claim 61 is directed to an isolated protein having at least 90% sequence identity to SEQ ID NO:23 or SEQ ID No.35, wherein the isolated protein is immunogenic.

Peak et al teach proteins from *Neisseria meningitidis* and pharmaceutical compositions containing the polypeptide (see the Abstract and pages 34-40). Peak et al teach a *N. meningitidis* protein (SEQ ID NO:21) that has the amino acid sequence that is 98.1% identity to SEQ ID NO:23.

```

Query Match          98.1%;   Score 2550.5;   DB 2;   Length 591;
Best Local Similarity 86.6%;   Pred. No. 4.1e-150;
Matches 512;   Conservative 0;   Mismatches 0;   Indels 79;   Gaps
1;

Qy          1 MNKIYRIIWNNSALNAWVVVSELTRNHTKRASATVKTAVLATLLFATVQASANNE----- 54
              |||
Db          1 MNKIYRIIWNNSALNAWVVVSELTRNHTKRASATVKTAVLATLLFATVQASANNEEQEEDL 60

Qy          55 ----- 54

Db          61 YLDPVQRTVAVLIVNSDKEGTGEKEKVEENSDWAVYFNEKGVLTAREITLKAGDNLKIKQ
120

```

Art Unit: 1645

Qy 55 -----TDLTSVGTEKLSFSANGNKVNITSDTKGLNFAKETAGTNGDTTVHLN  
101  
|  
Db 121 NGTNFTYSLKKDLTDLTSVGTEKLSFSANGNKVNITSDTKGLNFAKETAGTNGDTTVHLN  
180  
|  
Qy 102 GIGSTLTDTLLNTGATTNVTNDNVTDDDEKKRAASVKDVLNAGWNIKGVKPGTTASDNVDF  
161  
|  
Db 181 GIGSTLTDTLLNTGATTNVTNDNVTDDDEKKRAASVKDVLNAGWNIKGVKPGTTASDNVDF  
240  
|  
Qy 162 VRTYDTVEFLSADTKTTTVNVESKDNGKKTEVKIGAKTSVIKEKDGLVTGKDKGENGSS  
221  
|  
Db 241 VRTYDTVEFLSADTKTTTVNVESKDNGKKTEVKIGAKTSVIKEKDGLVTGKDKGENGSS  
300  
|  
Qy 222 TDEGEGLVTAKEVIDAVNKAGWRMKT T T TANGQTGQADKFETVTSGTNVTFASGKGT TATV  
281  
|  
Db 301 TDEGEGLVTAKEVIDAVNKAGWRMKT T T TANGQTGQADKFETVTSGTNVTFASGKGT TATV  
360  
|  
Qy 282 SKDDQGNITVMYDVNVGDALNVNQLQNSGWNLD SKAVAGSSGKVISGNVSPSKGKMDETV  
341  
|  
Db 361 SKDDQGNITVMYDVNVGDALNVNQLQNSGWNLD SKAVAGSSGKVISGNVSPSKGKMDETV  
420  
|  
Qy 342 NINAGNNIEITRNGKNIDIATSMTPQFSSVSLGAGADAP T LSVGDALNVGSKKDNKPVR  
401  
|  
Db 421 NINAGNNIEITRNGKNIDIATSMTPQFSSVSLGAGADAP T LSVGDALNVGSKKDNKPVR  
480  
|  
Qy 402 ITNVAPGVKEGDVTNVAQLKGVAQNLNNRIDNVDGNARAGIAQAIATAGLVQAYLPGKSM  
461  
|  
Db 481 ITNVAPGVKEGDVTNVAQLKGVAQNLNNRIDNVDGNARAGIAQAIATAGLVQAYLPGKSM  
540  
|  
Qy 462 MAIGGGTYRGEAGYAIGYSSISDGGNWI I KGTASGNSRGHFGASASVGYQW 512  
|  
Db 541 MAIGGGTYRGEAGYAIGYSSISDGGNWI I KGTASGNSRGHFGASASVGYQW 591

Peak et al teach a *N. meningitidis* protein (SEQ ID NO:21) that has the amino acid sequence that is 99.3% identity to SEQ ID NO:35.



Art Unit: 1645

```

Query Match          99.3%;   Score 2333;   DB 2;   Length 591;
Best Local Similarity 100.0%;   Pred. No. 5.5e-140;
Matches 458;   Conservative    0;   Mismatches    0;   Indels    0;   Gaps
0;

Qy          4 TDLTSVGTEKLSFSANGNKVNITSDTKGLNFAKETAGTNGDTTVHLNGIGSTLTDTLLNT 63
          |||
Db          134 TDLTSVGTEKLSFSANGNKVNITSDTKGLNFAKETAGTNGDTTVHLNGIGSTLTDTLLNT
193

Qy          64 GATTNVTNDNVTDDEKKRAASVKDVLNAGWNIKGVPKPGTTASDNVDFVRTYDTVEFLSAD
123
          |||
Db          194 GATTNVTNDNVTDDEKKRAASVKDVLNAGWNIKGVPKPGTTASDNVDFVRTYDTVEFLSAD
253

Qy          124 TKTTTVNVESKDNGKKTEVKIGAKTSVIKEKDGLVTKGDKGENGSSTDEGEGLVTAKEV
183
          |||
Db          254 TKTTTVNVESKDNGKKTEVKIGAKTSVIKEKDGLVTKGDKGENGSSTDEGEGLVTAKEV
313

Qy          184 IDAVNKAGWRMKT TTTANGQTGQADKFETVTSGTNVTFASGKGT TATVSKDDQGNITVMYD
243
          |||
Db          314 IDAVNKAGWRMKT TTTANGQTGQADKFETVTSGTNVTFASGKGT TATVSKDDQGNITVMYD
373

Qy          244 VNVGDALNVNQLQNSGWNLDSKAVAGSSGKVISGNVSPSKGKMDETVNINAGNNIEITRN
303
          |||
Db          374 VNVGDALNVNQLQNSGWNLDSKAVAGSSGKVISGNVSPSKGKMDETVNINAGNNIEITRN
433

Qy          304 GKNIDIATSMTPQFSSVSLGAGADAP TLSVDGDALNVGSKKDNKPVRITNVAPGVKEGDV
363
          |||
Db          434 GKNIDIATSMTPQFSSVSLGAGADAP TLSVDGDALNVGSKKDNKPVRITNVAPGVKEGDV
493

Qy          364 TNVAQLKGVAQN LNNRIDNVDGNARAGIAQAIATAGLVQAYLPGKSMM AIGGGTYRGEAG
423
          |||
Db          494 TNVAQLKGVAQN LNNRIDNVDGNARAGIAQAIATAGLVQAYLPGKSMM AIGGGTYRGEAG
553

Qy          424 YAIGYSSISDGGNWI IKG TASGNSRGHFGASASVG YQW 461
          |||
Db          554 YAIGYSSISDGGNWI IKG TASGNSRGHFGASASVG YQW 591

```

The protein and pharmaceutical compositions of Peak et al appear to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's protein and pharmaceutical compositions with the protein and pharmaceutical compositions of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein and pharmaceutical compositions of the prior art does not possess the same material structural and functional characteristics of the claimed protein and pharmaceutical compositions). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

5. Claim 61 is rejected under 35 U.S.C. 102(e) as anticipated by Peak et al (*U. S. Patent No.6,197,312 B1 published March 2001, filed August 19, 1999*).

Claim 61 is directed to an isolated protein having at least 90% sequence identity to SEQ ID NO:23 or SEQ ID No.35, wherein the isolated protein is immunogenic.

Peak et al teach proteins from *Neisseria meningitidis* and pharmaceutical compositions containing the polypeptide (see the Abstract and columns 16-18). Peak et al teach a *N. meningitidis* protein (SEQ ID NO:21) that has the amino acid sequence that is 98.1% identity to SEQ ID NO:23. The protein and pharmaceutical compositions of Peak et al appear to be the same as the claimed invention.

Art Unit: 1645

Query Match 98.1%; Score 2550.5; DB 2; Length 591;  
Best Local Similarity 86.6%; Pred. No. 6.2e-198;  
Matches 512; Conservative 0; Mismatches 0; Indels 79; Gaps 1;

Qy	1	MNKIYRIIWNSALNAWVVVSELTRNHTKRASATVKTAVLATLLFATVQASANNE-----	54
Db	1	MNKIYRIIWNSALNAWVVVSELTRNHTKRASATVKTAVLATLLFATVQASANNEEQEEDL	60
Qy	55	-----	54
Db	61	YLDPVQRTVAVLIVNSDKEGTGEKEKVEENSDWAVYFNEKGVLTAREITLKAGDNLKIKQ	
120			
Qy	55	-----TDLTSVGTEKLSFSANGNKVNITSDTKGLNFAKETAGTNGDTTVHLN	
101			
Db	121	NGTNFTYSLKDLTDLTSVGTEKLSFSANGNKVNITSDTKGLNFAKETAGTNGDTTVHLN	
180			
Qy	102	GIGSTLTDLLNTGATTNVTNDNVTDDDEKKRAASVKDVLNAGWNIKGVPKPGTTASDNVDF	
161			
Db	181	GIGSTLTDLLNTGATTNVTNDNVTDDDEKKRAASVKDVLNAGWNIKGVPKPGTTASDNVDF	
240			
Qy	162	VRTYDTVEFLSADTKTTTVNVESKDNGKKTEVKIGAKTSVIKEKDGLVTKDKGENGSS	
221			
Db	241	VRTYDTVEFLSADTKTTTVNVESKDNGKKTEVKIGAKTSVIKEKDGLVTKDKGENGSS	
300			
Qy	222	TDEGEGLVTAKEVIDAVNKAGWRMKTITANGQTGQADKFETVTSGTNVTTFASGKGTATV	
281			
Db	301	TDEGEGLVTAKEVIDAVNKAGWRMKTITANGQTGQADKFETVTSGTNVTTFASGKGTATV	
360			
Qy	282	SKDDQGNITVMYDVNVGDALNVNQLQNSGWNLDKAVAGSSGKVISGNVSPSKGKMDETV	
341			
Db	361	SKDDQGNITVMYDVNVGDALNVNQLQNSGWNLDKAVAGSSGKVISGNVSPSKGKMDETV	
420			
Qy	342	NINAGNNIEITRNGKNIDIATSMTPQFSSVSLGAGADAPTLSDGDALNVGSKKDNKPVR	
401			
Db	421	NINAGNNIEITRNGKNIDIATSMTPQFSSVSLGAGADAPTLSDGDALNVGSKKDNKPVR	
480			
Qy	402	ITNVAPGVKEGDVTNVAQLKGVAQNLNNRIDNVDGNARAGIAQAIATAGLVQAYLPGKSM	
461			
Db	481	ITNVAPGVKEGDVTNVAQLKGVAQNLNNRIDNVDGNARAGIAQAIATAGLVQAYLPGKSM	
540			

Art Unit: 1645

```
Qy      462 MAIGGGTYRGEAGYAIGYSSISDGGNWIIKGTASGNSRGHFGASASVGYQW 512
          |||
Db      541 MAIGGGTYRGEAGYAIGYSSISDGGNWIIKGTASGNSRGHFGASASVGYQW 591
```

Peak et al teach a *N. meningitidis* protein (SEQ ID NO:21) that has the amino acid sequence that is 99.3% identity to SEQ ID NO:35.

Query Match 99.3%; Score 2333; DB 2; Length 591;  
Best Local Similarity 100.0%; Pred. No. 3.7e-181;  
Matches 458; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

```
Qy      4 TDLTSVGTEKLSFSANGNKVNITSDTKGLNFAKETAGTNGDTTVHLNGIGSTLTDTLLNT 63
          |||
Db     134 TDLTSVGTEKLSFSANGNKVNITSDTKGLNFAKETAGTNGDTTVHLNGIGSTLTDTLLNT
193
```

```
Qy     123 64 GATTNVTNDNVTDDKKRAASVKDVLNAGWNIKGVKPGTTASDNVDFVRTYDTVEFLSAD
          |||
Db     253 194 GATTNVTNDNVTDDKKRAASVKDVLNAGWNIKGVKPGTTASDNVDFVRTYDTVEFLSAD
```

```
Qy     183 124 TKTTTVNVESKDNGKKTEVKIGAKTSVIKEKDGLVTGKDKGENGSSTDEGEGLVTAKEV
          |||
Db     313 254 TKTTTVNVESKDNGKKTEVKIGAKTSVIKEKDGLVTGKDKGENGSSTDEGEGLVTAKEV
```

```
Qy     243 184 IDAVNKAGWRMKT TTTANGQTGQADKFETVTSGTNVTFASGKGTATVSKDDQGNITVMYD
          |||
Db     373 314 IDAVNKAGWRMKT TTTANGQTGQADKFETVTSGTNVTFASGKGTATVSKDDQGNITVMYD
```

```
Qy     303 244 VNVDALNVNQLQNSGWNLDKAVAGSSGKVISGNVSPSKGKMDETVNINAGNNIEITRN
          |||
Db     433 374 VNVDALNVNQLQNSGWNLDKAVAGSSGKVISGNVSPSKGKMDETVNINAGNNIEITRN
```

```
Qy     363 304 GKNIDIATSMTPQFSSVSLGAGADAPTLSDGDALNVGSKKDNKPVIRITNVAPGVKEGDV
          |||
Db     493 434 GKNIDIATSMTPQFSSVSLGAGADAPTLSDGDALNVGSKKDNKPVIRITNVAPGVKEGDV
```

```
Qy     423 364 TNVAQLKGVAQNLNNRIDNVDGNARAGIAQAIATAGLVQAYLPGKSMMMAIGGGTYRGEAG
          |||
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Art Unit: 1645

Db 494 TNVAQLKGVAQNLNNRIDNVDGNARAGIAQAIATAGLVQAYLPGKSMMMAIGGGTYRGEAG  
553

Qy 424 YAIGYSSISDGGNWIIKGTASGNSRGHFGASASVGYQW 461

||||||||||||||||||||||||||||||||||||||||||  
Db 554 YAIGYSSISDGGNWIIKGTASGNSRGHFGASASVGYQW 591

Since the Office does not have the facilities for examining and comparing applicant's protein and pharmaceutical compositions with the protein and pharmaceutical compositions of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein and pharmaceutical compositions of the prior art does not possess the same material structural and functional characteristics of the claimed protein and pharmaceutical compositions). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1645

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Status of Claims***

7. Claims 33-34, 49-52, 54-55 and 57-60 are free of the cited art and are allowable.

***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa L. Ford whose telephone number is (571) 272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0856 the fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vanessa L. Ford/  
Patent Examiner, Art Unit 1645  
November 20, 2008

/Robert B Mondesi/  
Supervisory Patent Examiner, Art Unit 1645